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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,522	08/13/2001	Michael E. Spurlock	PM-8808-A	8379

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/928,522	SPURLOCK, MICHAEL E.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *6-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no search burden because the Examiner has not demonstrated that the inventions are separately classified in the art. This is not found persuasive because Applicant has offered no evidence as to which class/subclass the 4 inventions should be jointly classified in. First, Applicant is incorrect in the conclusion that the classification of the 4 inventions is in error. A review of issued patents in the art areas of DNA molecules, proteins, antibodies and antisense molecules will support the current assignment of the 4 claimed inventions as presented in paper #9. Additionally, the assignment given in paper #9 was indicated as "for example", which means that these are classes that the claimed invention may be classified, but is not necessarily the final designation of classification. For example, Group I is directed to DNA molecules, vectors containing said DNA molecules, and host cells containing said vectors. It is noted that the claims of Group I do not include an actual method of protein production using the host cell, but this would be implied by way of claiming the host cell, so the classification of 435/69.1 was used, "for example". The DNA molecule encoding porcine leptin could also be classified in 536/23.5, the vector could be classified in 435/320.1 and the host cells could be classified in a number of locations depending on the cell which is used. However, the inventions of Groups II-IV would not be found under any of these classifications, thereby showing different classification. Next, Applicant argues that antisense RNA is not properly classified in

514/44 because there is no recitation of a carbohydrate. Applicant is incorrect because the structure of DNA and RNA molecules is based on a sugar backbone, and therefore, inherently possesses a carbohydrate structure. As class 514, subclass 44 specifically states, it is directed to "polynucleotide (e.g., RNA, DNA, etc.)", this would be the proper classification. If Applicant has concerns regarding this designation, Applicant is invited to contact the PTO Classification Operations at (703) 305-5107. Lastly, Applicant asserts that the classification of 530/387.1 is incorrect for the antibodies of Group IV because there is no mention of "blood antibody". This argument does not make sense and may be the result of the lack of familiarity in the art of antibodies. Subclass 380 is directed to two molecules, (1) blood proteins and (2) globulins. Further subclasses break out the various blood proteins, such as proteins involved in coagulation. Next comes globulins (subclass 386), which is further broken down into types of globulins as well as characterizations based on the binding properties of the globulins. Therefore, subclass 387.1 is the first indent under globulins which is directed to antibodies, and is the proper classification for a claim to an antibody as defined in claim 12.

Therefore, Groups I-IV were properly classified, establishing a *prima facie* case of burden. Likewise, separate field of search can be established based on the lack of common structure of the compounds and lack of common function of the 4 different inventive Groups. Applicant may be attempting to argue that there is no search burden for examination of Groups I-IV because each invention of each Group would be obvious over one another. However, Applicant may want to exert caution in an admission of this

kind, as art applied to any one of the inventions would then be art against the other invention based on Applicant's own admission.

The requirement is still deemed proper and is therefore made FINAL.

Priority

It is noted that this application claims subject matter disclosed in prior Application No. 08/688,908, filed 31 July 1996. The reference to the prior application is present as the first sentence of the specification of this application. However, the current status of all nonprovisional parent applications referenced should be included. The current status of the parent application, now U.S. Pat. No. 6,297,027 is missing.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is longer than 150 words. Correction is required. See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,297,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims encompass common subject matter which is fully disclosed in the patent. The claims of the issued patent are directed to nucleic acid molecules (DNA or RNA) consisting of a nucleotide sequence which encodes a bovine adipocyte polypeptide leptin having the amino acid sequence of SEQ ID NO:4 (as well as expression vectors, and host cells containing these molecules) or having the nucleic

acid sequence of SEQ ID NO:3. The instant claims are directed to nucleic acid molecules (DNA or RNA) consisting of a nucleotide sequence which encodes a bovine adipocyte polypeptide leptin consisting of the nucleotide sequence of SEQ ID NO:3 or an allelic variant thereof. Therefore, the subject matter of SEQ ID NO:3 is the same, and the claims substantially overlap and claim common subject matter. Therefore, the instant claims would be prima facie obvious and, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In so far as the instant claims are directed to allelic variants of SEQ ID NO:3, the specification lacks an adequate written description of this subject matter. The recitation of "allelic variant" is directed to a specific molecule for which the instant specification fails to describe the molecule in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. The structure of an "allelic variant" cannot be predicted on the basis of the nucleotide sequence of SEQ ID NO:3 since there is no disclosure of where the variation occurs in the sequence of SEQ ID NO:3. The claims are directed to a species of nucleic acid, the structure of which cannot be determined or predicted from the disclosed nucleic acid sequence and the specification does not evidence isolation or conception of the structure of an "allelic variant", therefore, the specification does not provide an adequate written description of the claimed subject matter, and thus the claimed invention, to the extent that it reads upon an "allelic variant" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

With the exception of very particular nucleic acid sequence which is disclosed in the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel, 25

USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) The instant claims are directed to a structure, which could be isolated, but for which, there is no written description. As in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. In the instant situation, the specification only provides a single nucleic acid sequence, but fails to provide a description of the "broad class" of allelic variants, regardless of whether they could be made or isolated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by TELLAM et al. (Genbank Acc. No. U43943, Bos taurus OBESE mRNA, 27 January 1996).

TELLAM et al. disclose a nucleic acid molecule (mRNA) which is an allelic variant of SEQ ID NO:3 of the instant application. The nucleotide sequence differs from that of SEQ ID NO:3 in length (the prior art is longer) and differs in sequence at 14 positions. This translates into 2 amino acid differences (see bolded amino acids in the attached reference) and 18 additional amino acids at the N-terminus of the protein, which could be leader sequence. Therefore, the instant claim is anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over TELLAM et al. (Genbank Acc. No. U43943, Bos taurus OBESE mRNA, 27 January 1996).

TELLAM et al. disclose a nucleic acid molecule (mRNA) which is an allelic variant of SEQ ID NO:3 of the instant application. TELLAM et al. do not disclose single or double stranded DNA, an expression vector or plasmid comprising the DNA or a host cell transformed or transfected with the plasmid. However, at the time of the instant invention, it would have been *prima facie* obvious to one of ordinary skill in the art to use the mRNA molecule of TELLAM et al. to generate a DNA molecule, which could then be placed into an expression vector or plasmid, and then placed into a host cell for the

purpose of propagating the nucleic acid, as well as for expression of the encoded protein of the nucleic acid of TELLAM et al. One would be motivated to do this because TELLAM et al. identify the nucleic acid as encoding bovine obesity protein (a.k.a. leptin) and this protein is known to be valuable in regulation of weight in mammals. At the time of the instant invention, such methods and techniques were old and well-known in the art, as evidenced by the disclosure of the instant specification at pages 9-10, therefore, a reasonable expectation of success was also present.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud